PRESS RELEASE, June 21, 2018

AcuCort signs agreement with the CRO Quinta-Analytica concerning the performance of bioequivalence studies

AcuCort AB (AktieTorget: ACUC) today announces that the company has signed a collaboration agreement with the Czech CRO (Contract Research Organization) Quinta-Analytica s.r.o. concerning the performance of the bioequivalence studies that will form the basis for the applications for market approval for AcuCort's drug candidate Dexa ODF in the EU and the US. Dexa ODF is a fast-dissolving oral film to be placed on the tongue for the treatment of acute allergic reactions.

In order to apply for market approval in the EU and the US AcuCort needs to demonstrate bioequivalence between Dexa ODF and a previously approved reference drug containing the same active substance – dexamethasone. Bioequivalence is a term used when two compared drugs function in a similar way in the body according to established criteria. Bioequivalence studies offer a cost-effective and considerably faster way to approval compared to traditional clinical efficacy studies.

"The choice of CRO for the planned bioequivalence studies is of great importance to AcuCort. We have evaluated a number of possible candidates and after thorough analysis we have come to the conclusion that Quinta-Analytica is the best partner. Through this choice of new partner AcuCort ensures a high quality, experienced and cost-effective performer of the bioequivalence studies who can help us with one of the most important steps towards market approval, according to the schedule that we have communicated," says Mats Lindfors, CEO of AcuCort.

"I would like to thank AcuCort for the trust placed in us as a partner for the upcoming bioequivalence studies. With more than 170 completed studies since 2006, we are convinced that Quinta-Analytica is the right partner for this type of studies. We are honored and firmly committed to deliver reliable results in collaboration with AcuCort according to schedule to support AcuCort in their efforts to reach the market with their product. I am convinced that our solid experience will contribute to a successful collaboration," says Roman Grunt, CEO of Quinta-Analytica.

The bioequivalence studies are planned to start during the second half of 2018 following the production of a number of batches of Dexa ODF according to Good Manufacturing Practice,

GMP. Before the start of studies for approval in the US a pre-meeting with the US Food and Drug Administration, FDA, is planned.

For more information, please contact

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About the market for Dexa ODF

Every year millions of patients across the world use medicines containing glucocorticoids. A large area of application is for the rapidly growing group of allergy patients and patients with viral croup. Also, cancer patients suffering from nausea and vomiting in connection with chemotherapy (CINV) use this type of drug. One big disadvantage is that these drugs are not perceived to be user-friendly, or require medical staff. First having to dissolve the tablets in water can be very awkward in an acute situation, for the sufferers as well as for other persons helping them. The patients may have difficulties swallowing, and thus a fast-dissolving film to be placed on the tongue, with the same effect as the tablet, may have a wide application area.

About AcuCort

AcuCort develops and commercializes Dexa ODF, a new fast-dissolving oral film containing the glucocorticoid dexamethasone. Dexa ODF is a smart product in a new, innovative, patented and user-friendly dosage form, primarily for the treatment of acute allergic reactions, viral croup in children and chemotherapy-induced nausea and vomiting (CINV). Dexa ODF is estimated to have a short time to market as the company only has to repeat a previously successful bioequivalence study before applying for market approval in Europe. Please visit www.acucort.com.

About QUINTA-ANALYTICA s.r.o.

Founded in 1997, Quinta-Analytica is today an established provider of services in a number of research and development areas, and clinical and regulatory services for pharma, biotechnology and generics companies. Quinta-Analytica has been audited several times by the US Food and Drug Administration, FDA, without remarks. The main area of operation is pharmacological studies in man at own clinic and bioanalyses in own laboratory. The company also performs drug testing including method development and transfer, batch release, stability studies, analyses in the areas of inhalation, anti-asthmatics, peptides and proteins. The company also offers consultancy services concerning clinical strategy and regulatory issues. Since 2006 the company runs its own integrated clinic and has completed more than 170 bioequivalence and pharmacokinetics studies. The company is headquartered in Prague, the Czech Republic. Please visit www.quinta.cz.